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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/289,180	04/09/99	SHIMOKAWATOKO	Y 2185-0324P-S

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BIRCH STEWART KOLASCH & BIRCH
P O BOX 747
FALLS CHURCH VA 22040-0747

EXAMINER
TUNG, P

ART UNIT	PAPER NUMBER
1652	7

DATE MAILED: 11/24/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/289,180

Applicant(s)
Shimokawatoko et al.

Examiner
Peter Tung

Group Art Unit
1652



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-27 is/are pending in the application.

Of the above, claim(s) 8-27 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-7 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, drawn to a method of evaluating a compound for protoporphyrinogen oxidase inhibitory activity, classified in class 435, subclass 4.
 - II. Claims 8-17, drawn to DNA encoding a rat protoporphyrinogen oxidase (SEQ ID NO: 2 and DNA encoding SEQ ID NO: 1), vectors comprising said DNA and transformed host cells, classified in class 536, subclass 23.2.
 - III. Claims 8-17, drawn to DNA encoding a *Chlamydomonas* protoporphyrinogen oxidase (SEQ ID NO: 10 and DNA encoding SEQ ID NO: 9), vectors comprising said DNA and transformed host cells, classified in class 536, subclass 23.2.
2. The inventions are distinct, each from the other because of the following reasons:

Each of Groups II and III is directed to a separate and distinct invention. Group II is directed to DNA encoding a rat protoporphyrinogen oxidase and Group II is directed toward DNA encoding a *Chlamydomonas* protoporphyrinogen oxidase.

The products of Group II and III have distinct morphological, functional, chemical and physical properties. These products are capable of separate manufacture, use, or sale as claimed, and are patentably distinct.

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3. Inventions of Group II and Group I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process such as heterologous production of protoporphyrinogen oxidase.

4. Inventions of Group III and Group I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process such as heterologous production of protoporphyrinogen oxidase.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group is not required for Group , restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Mr. Gerald Murphy on 9/17/99 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-7. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8-27 are

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withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

8. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

9. The following correction in the sequence computer readable form have been corrected by the STIC systems branch:

Corrected the SEQ ID NO when obviously incorrect. The sequence numbers that were edited were: 2.

Corrected a nucleic number at the end of a nucleic line. SEQ ID NO's edited: 2.

Deleted non-ASCII "garbage" at the beginning and end of files.

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10. The use of the trademarks "Marathon" cDNA amplification kit, page 19, line 12; "DIG-High Prime DNA Labeling and Detection Starter Kit I," page 22, line 7-8; "MicroSpin S-400HR," page 34, line 13, among others, has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Adequate description for the species encompassed by the claim would have relevant identifying characteristics which include 1) structure, 2) physical and/or chemical characteristics, 3) functional characteristics when coupled with a known or disclosed correlation between function and structure, 4) a combination of these. The instant claims are drawn to a protoporphyrinogen oxidase gene and to a gene which is capable of controlling transcriptional

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activity of a promoter. However, the structure of a gene entails more than just the coding sequence of a protein but also includes the regulatory, promoter and terminator sequences that precede and follow the coding sequence. For a eukaryotic gene, intervening sequences would also be expected. Adequate description of the structure of the gene would include all of these sequences. The instant application discloses protoporphyrinogen oxidase encoding sequences of DNA but not intervening, regulatory, promoter and terminator sequences. A gene which is capable of controlling transcriptional activity of a promoter would also comprise more than just a coding sequence. Therefore the complete structure of the gene is inadequately described.

Claim 5 is drawn to protoporphyrinogen oxidase DNA obtained from an animal or plant. An insufficient representative number of species of the DNA encoding protoporphyrinogen oxidase are provided as only one rat and one plant DNA encoding protoporphyrinogen oxidase is disclosed. Therefore there is inadequate description of the claimed species of DNA.

Claim 7 is drawn to a microorganism host cell that has a deficient protoporphyrinogen oxidase. As only *E. coli* and yeast deficient in protoporphyrinogen oxidase are disclosed, an insufficient representative number of species of microorganism host cells deficient in protoporphyrinogen oxidase are disclosed. Therefore there is inadequate description of the claimed species of microorganism host cells.

13. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the amount of direction or guidance presented, (2) the nature of the invention, (3) the state of the prior art and (4) the predictability or unpredictability of the art. A compound's ability to inhibit a heterologous protoporphyrinogen oxidase expressed in a host cell deficient in protoporphyrinogen oxidase activity cannot be correctly evaluated by comparing the growth rates between the host cell grown in the presence of a test compound and the host cell grown in the absence of the test compound. As compounds may affect the growth of the host cell through other means besides inhibition of protoporphyrinogen oxidase, the ability of a compound to inhibit protoporphyrinogen oxidase would not necessarily be evaluated by the claimed method. Insufficient guidance is provided on how to determine if a compound that affects host cell growth rates is actually inhibiting protoporphyrinogen oxidase. There is unpredictability in determining whether a compound is an inhibitor of protoporphyrinogen oxidase in a host cell when growth rates are compared between host cells in the presence and absence of a compound as a compound may affect growth by a means besides protoporphyrinogen oxidase inhibition.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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15. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
16. Claims 1-4 is unclear as what is meant by "...comparative system of the presence and absence of a test compound..."
17. Claims 1-4 recite the limitation "condition" in line 6. There is insufficient antecedent basis for this limitation in the claim.
18. Claims 5-7 are indefinite because they depend upon an indefinite base claim and fail to correct the problem.
19. No claims are allowed.
20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600